REGULATORY IMPACT ASSESSMENT GUIDE

Why CONDUCT Regulatory Impact Assessment (RIA)?

Guide for the Medical Technology Sector

Standards Alliance | ATCET-2026

WHY CONDUCT REGULATORY IMPACT ASSESSMENT (RIA)?

PRESENTATION

The Regulatory Impact Assessment (RIA) Guide for the Medical Technology Sector was developed under the auspices of the Inter-American Coalition for Regulatory Convergence, Medical Technology Sector (Coalition) as part of ongoing efforts to strengthen Good Regulatory Practices (GRPs), regulatory convergence, and reliance mechanisms across the Americas.

The Guide also contributes to the objectives of the Advanced Training for Medical Device Regulators Around Critical and Emerging Technologies 2026 (ATCET-2026) project, approved under the Standards Alliance, a public-private partnership between the American National Standards Institute (ANSI), the U.S. Department of State and the Advanced Medical Technology Association (AdvaMed), and a continuation of the Medical Device Regulatory Convergence Project (MDRC, 2019–2024).

Purpose

The Guide provides medical device regulators and stakeholders with a practical framework for conducting Regulatory Impact Assessments that support evidence-based decision making, proportional regulation, and continuous regulatory improvement. It emphasizes that RIA should not be viewed as a procedural formality, but as a tool to identify problems, evaluate alternatives, assess impacts, and select the most effective regulatory solutions.

Relevance to ATCET-2026

The Guide directly supports ATCET-2026 objectives by:

- Advancing the implementation of Good Regulatory Practices (GRPs).
- Promoting regulatory convergence and reliance in medical device regulation.
- Encouraging the use of internationally recognized standards and best practices.
- Supporting capacity building for regulators and stakeholders.
- Helping identify opportunities to streamline regulatory processes while maintaining high standards of patient safety and public health protection.
- Facilitating the practical use of international references, standards, and reliance mechanisms as tools to improve regulatory efficiency and effectiveness.

Expected Outcomes

By strengthening medical device regulators' capacity to conduct high-quality RIAs, the Guide aims to support regulatory frameworks that are more transparent, predictable, evidence-based, and aligned with international best practices, ultimately improving patient access to safe and innovative medical technologies while reducing unnecessary regulatory burdens.

INDEX

1. INTRODUCTION

1.1 PURPOSE OF THE GUIDE: RIA AS AN EVIDENCE-BASED DECISION SUPPORT TOOL

The Regulatory Impact Assessment (RIA) is not a mere questionnaire or a formality to justify the creation of a rule. RIA is a systematic, flexible, evidence-based management process built to diagnose a real problem, identify options of solution, and thoroughly investigate the impacts—both positive and negative—of each alternative before making a decision.

The main purpose of this guide is to equip regulators so that their institutional decisions are based on an increasingly technical basis. The use of RIA can raise the quality of regulation, aiming to ensure that the costs of intervention are reasonable and proportional to the benefits delivered to society. It has the potential to avoid the imposition of unnecessary rules that unjustifiably burden the regulated sector and the state itself. RIAs can also help to avoid unintended consequences from regulations, not just preventing unnecessary rules altogether.

> ***Practical example:*** *Imagine that the health authority identifies failures in the reprocessing of single-use medical devices. Instead of immediately issuing a restrictive rule (command and control), the RIA encourages the regulator to map the problem, collect data, and assess whether simpler alternatives — such as information campaigns, issuance of good practice guides, or self-regulation of the sector — could mitigate the health risk with a lower cost of adaptation and inspection.*

1.2 THE IMPORTANCE OF RIA IN THE MEDICAL TECHNOLOGY SECTOR: BALANCING PATIENT SAFETY, REASONABLE COSTS, AND TECHNOLOGICAL INNOVATION

The medical technology and healthcare products sector poses unique challenges for regulation. It is a market with a high diversity of items, varied technical characteristics and an extremely accelerated technological evolution. For example, health products often have frequent incremental innovations and short life cycles, with an average of 18 to 24 months on the market before new generations of technology emerge.[i]

In this dynamic scenario, the application of the RIA is critical to design rules that do not quickly become obsolete and that do not block scientific advancement. Inefficient or overly rigid regulations double the risk of causing shortages of existing essential products and delaying patients' access to new technologies indispensable for the most effective treatment of diseases. The daily challenge of the medical technology regulator is to use RIA to find the delicate balance between ensuring maximum protection for patient safety and maintaining market attractiveness, competitiveness and innovation.

Practical example:

a) Orthopedic Implants: By observing the speed of innovations in the orthopedic area, the application of an RIA demonstrated that the lack of regulatory predictability to the group of products prevented the commercialization of technologies, which in turn minimized surgical risk. The analysis supported the creation of standards that could absorb these innovations, aiming at reducing surgery time and, therefore, at a lower exposure and risk of infection for the patient.

b) Medical Software (SaMD): Software has accelerated global and virtual distribution. Standardized, unsubstantiated risk-based regulation could severely hamper innovation in the industry. Using the RIA to clearly define risk scopes and criteria in line with international best practices can help ensure safety and efficacy without strangling technological development.

1.3 PRINCIPLES OF GOOD REGULATORY PRACTICES: TRANSPARENCY, PREDICTABILITY AND FOCUS ON RESULTS

Excellent regulation works by minimizing potential barriers and distortions, operating with clarity and focusing on the development of the sector. For this to occur in the medical technology environment, RIA must be anchored in three fundamental principles of good regulatory practices:

i. **Transparency (and Public Participation):** Regulatory construction cannot happen behind closed doors. Transparency means clearly communicating problems, ensuring accessible information, using simple language, and fostering genuine societal engagement. Listening to industry, healthcare providers, and patients in the early stages helps avoid unintended consequences, reduces failures, and provides valuable data for accurate cost estimates.

ii. **Predictability:** A highly innovative market needs planning. Regulatory unpredictability generates insecurity, inhibits investment, and blocks the entry of innovative products that minimize risks to patients. The use of RIA clearly demonstrates the "rule of the game", providing the sector with the stability it needs to invest in research and development in the long term.

iii. **Focus on Results (Proportionality):** The regulatory authority must intervene only where there is a need, always based on solid data (evidence-based regulation) and within the limit strictly necessary to remedy the identified failure. Rather than requiring blind compliance with bureaucratic rules ("doing things prescriptively"), outcome-focused regulation effectively aims to solve the social and public health problem. A results-oriented approach can move away from the classic and onerous model of state "command and control" by adopting flexible regulatory measures. Such models provide a better combination between the industry's freedom to innovate and the informational protection necessary for hospitals and patients, in compliance with the principle of proportionality.

iv. **Objectivity and Impartiality (Being Unbiased):** As a regulatory authority, your role is to mediate conflicting interests—such as those of the industry, patients, and the government itself. Therefore, objectivity and impartiality (the concept of being "unbiased") are not just best practices; they are fundamental principles of Good Regulatory Practices (GRPs). It is precisely this unbiased approach that protects your agency against claims of arbitrary action and "regulatory capture"—the risk of a regulation serving a specific interest group rather than society as a whole. Without limitation to other phases of the RIA, there is critical importance of objectivity and an unbiased approach in three practical stages: in the collection and use of evidence (Unbiased Information); in methodology as a "shield" for the public servant, and; in conducting public participation.

> ***Practical example:*** *If your agency is evaluating the cybersecurity risk of a new hospital software, it is not unbiased to base the RIA report solely on security tests provided and funded by the manufacturing company itself. An objective regulator will also seek independent statistics on hospital incidents, academic databases, or incident reports from other government agencies to validate that information and ensure it is impartial.*
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> ***Practical example:*** *During a public hearing to discuss restrictions on the reuse of surgical materials, the agency official leading the table should not aggressively debate with hospital representatives by stating that "the current practice is absurd and will be banned." Your posture must be neutral and focused on objective data collection. You should ask questions like, "What infection control data does the hospital have to prove the safety of reuse across 10 surgical cycles?" This captures raw evidence to be objectively judged later.*

By acting objectively and in an unbiased manner, you avoid creating rules based on guesswork or pressure from the strongest parties, shielding the regulatory process against judicial challenges and ensuring citizens' trust in the State's decisions.

2. THE RIA PROCESS: A QUALITY-ORIENTED APPROACH

2.1 FORMAL ASPECTS: RIGOR IN THE FULFILLMENT OF PROCEDURAL REQUIREMENTS

For a Regulatory Impact Assessment (RIA) to be truly useful and guide good decisions, it is not sufficient that it is merely carried out; it needs to be of high quality. The formal dimension of a RIA requires rigorous adherence to structural steps: defining the problem and its causes, establishing measurable objectives, identifying regulatory alternatives, and comparing these alternatives.[ii]

Literature reviewing the quality of RIAs shows that analyses frequently present critical weaknesses and inconsistencies in formal aspects. A common failure is the lack of detail when defining the problem, often describing it in generic ways without clearly identifying the market failures or systemic issues[iii] that justify public intervention. Another frequent procedural flaw is failing to adequately identify and discuss regulatory alternatives; in many instances, authorities only analyze the proposed regulation without considering any other options, including the "do nothing" baseline.[iv] Even in instances where the authority has properly diagnosed a specific problem, RIAs often fail to properly estimate the regulatory resources required to effectively implement proposed regulatory solutions without creating unintended health and trade barriers larger than the original problem.

> ***Practical example:*** *When setting objectives for a new medical software regulation, a rigorous formal approach requires defining a SMART (Specific, Measurable, Assignable, Realistic, Time-related) objective. Instead of a vague goal like "improve software safety," the authority should establish a specific target, such as "reduce the number of severe adverse events caused by diagnostic software by 30% within two years". Clear definitions of objectives are essential for monitoring the results of the regulation later.*

2.2 USEFULNESS FOR DECISION MAKING: HOW THE RIA SHOULD EFFECTIVELY INFLUENCE THE AUTHORITIES' CHOICE

A RIA is not a substitute for political decision-making, nor does it replace the judgment of regulatory authorities; rather, it informs the final choice of decision-makers with structured evidence and stakeholder inputs. Its core usefulness lies in providing the necessary knowledge so regulators can transparently assess whether a given regulation will achieve its objectives with acceptable impacts and reasonable costs.

However, if the RIA is poorly integrated into the decision-making process, it becomes merely symbolic and fails to improve existing regulatory structures. Conversely, studies indicate a high correlation between the quality of the RIA and its actual use by decision-makers: authorities are much more willing to base their choices on analyses when they are well-crafted.[v] A useful RIA must clearly present the trade-offs between different choices, allowing for a well-founded decision that maximizes social welfare.

Practical example: *In the case of cycling helmets evaluated by the Brazilian authority INMETRO, the RIA process challenged the initial assumptions about the need to intervene with classic, binding regulations. By gathering data on consumer risk perception and evaluating the delivery chain, the RIA led the authority to choose an information campaign instead of mandatory rules. This demonstrates how an evidence-based analysis can effectively pivot a regulatory decision toward a more efficient, non-regulatory alternative.*

2.3 INSTITUTIONALIZATION AND CULTURAL CHANGE: RIA BEYOND THE FULFILLMENT OF CHECKLISTS

For RIA to reach its full potential, it must go beyond a simple bureaucratic "checklist" exercise used only to justify predetermined regulatory choices. Evaluating a RIA strictly through compliance checklists often fails to identify critical quality problems, as a report might check all the required boxes but still contain low-quality, superficial content.[vi]

Therefore, successfully implementing RIA requires a profound cultural change within regulatory institutions. It involves adopting a mindset that views an informed, evidence-based process as an absolute necessity for achieving better regulatory outcomes. This cultural shift relies on securing strong political commitment, ensuring ongoing monitoring and evaluation, and embedding RIA into the administration's capacity-building mechanisms. Furthermore, true institutionalization demands "regulatory humility" from authorities—acknowledging cognitive biases, actively seeking external evidence, and recognizing the limits of controlling unintended consequences.[vii]

Practical example: *Instead of automatically drafting a prescriptive standard for a new medical device, an institution with a mature RIA culture will first pause to question whether the issue stems from a market failure or a regulatory inefficiency. The authority will openly consult stakeholders early in the process—before their minds are set on a particular intervention—to challenge their own assumptions, explore flexible alternatives, and embrace regulatory humility.*

3. STEP-BY-STEP APPROACH

STEP 1: IDENTIFICATION AND DEFINITION OF THE REGULATORY PROBLEM AND AFFECTED ACTORS

The starting point of any good Regulatory Impact Assessment (RIA) is correctly understanding the problem that triggered the need for action. A common mistake made by regulators is to define the problem simply as the "lack of a regulation" or the absence of a specific rule. Defining a problem as "the absence of a solution" limits your perspective and prevents you from finding the most effective, least burdensome response. Instead, a problem must be described as an undesirable situation occurring in the real world, such as a market failure, an institutional flaw, or an unacceptable risk to public health.[viii]

To successfully define the problem, you should break this step down into three key actions:

a) Identify root causes and consequences: To truly solve a public health or market problem, you must act on its root causes, not just its symptoms. There are many methodological paths to identify the real problem, and the regulator should identify the best tool for the applicable situation, on a case-by-case basis. A highly recommended visual tool for this is the "Problem Tree" diagram. In this framework, the core problem is represented as the trunk of the tree, the underlying causes are the roots, and the consequences (the negative impacts on society) are the branches. You can also use techniques like the "Five Whys" to dig deeper into the actual systemic issues driving the problem.

> ***Practical example:*** *Imagine your core problem is "Difficulties in managing health risks related to reprocessed single-use medical devices". The consequences (the branches) might include increased hospital infection rates, prolonged hospital stays, and adverse events for patients. If we look at the root causes (the roots), we might find confusing product labeling, lack of technical capacity and equipment in hospital sterilization centers, or financial pressures to reduce hospital costs. By mapping this out visually, the regulator can see exactly where an intervention*

b) Risk-based approach: In the medical technology sector, protecting patient safety is the primary goal, meaning that risk assessment must be a core part of defining the problem. In regulatory terms, risk is calculated by combining two dimensions: the probability of an adverse event occurring, and the severity (or impact) of the harm it causes if it does occur. Regulators must

evaluate these two factors to decide if the current risk is unacceptable and if an intervention is urgent.

> ***Practical example:*** *Let's assess the risk of some diagnostic software (Software as a Medical Device - SaMD) malfunctioning in a hospital environment. If the software contains a flaw that leads to an incorrect diagnosis and subsequent erroneous treatment, the severity of the harm could be critical, potentially leading to permanent injury or death. Even if the probability of the software bug manifesting is low, the high severity of the consequence classifies this as an unacceptable risk, clearly justifying the need for regulatory action to require validation and quality controls.*

c) Map the affected agents: A regulatory problem never exists in a vacuum; it affects multiple groups across the healthcare value chain, both positively and negatively. Mapping these stakeholders early in the RIA process is crucial because it helps you understand how the problem impacts them, whether their behavior contributes to the problem, and how they might react to future rules.

> ***Practical example:*** *When addressing the regulation of implantable orthopedic materials, your stakeholder map should list:*
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> - ***Patients:*** *The end-users who suffer directly from surgical risks, extended recovery times, or lack of access to innovative, safer implants.*
> - ***Hospitals and Health Professionals****: The entities and individuals utilizing the devices, who face operational challenges, rely on accurate information for patient safety, or bear liabilities if a product fails.*
> - ***Manufacturers and Importers:*** *The regulated industry that must navigate the rules. They face compliance costs but also rely on regulatory predictability to introduce innovative products into the market.*
> - ***Public Administration / Regulators:*** *Entities like health ministries, sanitary agencies, and the unified health system (e.g., SUS in Brazil) that must monitor the market, enforce the rules, and absorb the financial costs of adverse events.*

STEP 2: DEFINING THE OBJECTIVES OF THE REGULATORY INTERVENTION

Once you have diagnosed the problem, you must define exactly what the regulatory intervention aims to achieve. This step is essential to ensure that your agency's actions are focused, justified, and capable of being evaluated in the future.

Turn the negative statement of the problem into positive, clear, and measurable goals: The simplest way to start is by transforming the negative declaration of the problem you found into a positive declaration of objectives.[ix] To do this effectively, is possible to use the SMART framework (Specific, Measurable, Assignable, Realistic, Time-related).[x]

Instead of setting vague goals like "improve the regulatory environment" or "optimize efforts"— which leave room for ambiguity and make it impossible to measure results—you must state exactly what you want to achieve using measurable parameters. By establishing clear baselines and targets, you guarantee that the success of the regulation can be objectively monitored later.[xi]

Logical connection: Ensure that the achievement of objectives directly addresses the causes: There must be a clear hierarchy and logical link between the problem identified in Step 1 and the objectives set in Step 2. The general objective must aim to solve or mitigate the core problem itself. The specific objectives, on the other hand, must act as the exact steps to achieve the general goal by directly attacking the root causes you previously mapped. This logical connection ensures that your regulatory intervention will treat the real source of the issue, rather than just masking its symptoms.

Strategic alignment: Verify that the objectives are in line with public health policies: A good regulatory objective does not exist in a vacuum; it must reflect society's needs and values. You must verify that your objectives are completely aligned with broader public health and patient safety policies, as well as with your agency's statutory duties and strategic planning. This guarantees that the regulation will contribute to the overarching goals of the national health system, such as ensuring safe access to health technologies and reducing morbidity.

Practical Examples in the Medical Technology Sector:

1: Reprocessing of Single-Use Medical Devices

- ***Core Problem (Negative Statement):*** Difficulties in managing health risks related to the safety and efficacy of processed medical products, leading to adverse events and hospital infections.
- ***General Objective (Positive Statement):*** Improve the agency's regulatory governance regarding the management of risks associated with product processing.
- ***Specific Objectives (Attacking Root Causes):*** Reduce information asymmetry about processed products; induce a culture of Good Processing Practices in health services based on a risk approach; and establish a clear, national sanitary policy regarding the reprocessing of devices originally labeled as single-use.

2: Medical Software (Software as a Medical Device - SaMD)

- ***Core Problem (Negative Statement):*** The accelerated and disruptive innovation of medical software rendered traditional hardware-focused rules obsolete, creating vulnerabilities and cybersecurity risks for patients.
- ***General Objective (Positive Statement):*** Prevent or mitigate the health risks arising from the use of medical software.
- ***Specific Objectives (Attacking Root Causes):*** Align the national regulatory model with international practices (such as the IMDRF guidelines); establish minimum security and efficacy requirements to regulate cybersecurity in connected devices; and define clear transparency mechanisms for interoperability and data portability.

3: Custom-Made Medical Devices

- ***Core Problem (Negative Statement):*** Absence of a specific framework to regulate custom-made products, making the control of patient-specific risks difficult.
- ***General/Specific Objective (Positive/Strategic Alignment):*** Establish clear requirements for the manufacturing, commercialization, and import of custom-made and patient-specific medical devices, enabling faster access to customized treatments for patients while maintaining patient safety controls equivalent to series-manufactured products.

STEP 3: MAPPING AND DESCRIPTION OF ALTERNATIVES

When faced with a regulatory problem, the immediate reflex of many authorities is to simply draft a new normative act or decree. However, a high-quality Regulatory Impact Assessment (RIA) requires regulators to step out of this traditional "command and control" mindset and creatively explore various avenues to solve the problem.

The goal of this step is to map all feasible alternatives, prioritizing those that are less burdensome and more flexible, while explicitly discarding unviable options with clear justifications. By assessing multiple paths, the regulator ensures that the chosen intervention is strictly proportional to the problem and does not create unnecessary barriers to technological innovation.

1. The Baseline: "No Action" (Maintaining the Status Quo): You must always include the "No Action" (or "do nothing") alternative in your RIA. This option does not necessarily mean the problem is ignored; rather, it represents the scenario of how the problem will naturally evolve over time without any new intervention from the regulatory agency**.**

The "No Action" option serves as the mandatory baseline for your analysis. Every other regulatory or non-regulatory alternative must be compared against this baseline to prove that the proposed intervention actually generates superior net benefits. If the costs of acting are higher than the benefits, maintaining the status quo is the correct regulatory decision.[xii]

2. Non-Normative Alternatives: Before considering strict rules, authorities should evaluate non-normative options. These are strategies that use incentives, education, or shared responsibilities to change the behavior of economic agents without issuing prescriptive state mandates, generally resulting in lower administrative costs**.**

Information and Education: Sometimes the root cause of a market failure is just a lack of information (information asymmetry). The regulator can solve the problem by educating the public or increasing transparency.

> ***Practical Example:*** *In Brazil, instead of creating rigid price caps for implantable orthopedic devices—which could discourage innovation and cause shortages of advanced technologies—the regulator opted to create a public monitoring panel displaying the technical attributes and prices of similar devices. This non-normative approach empowered hospitals to make better purchasing choices and naturally reduced-price dispersion without heavy-handed market intervention. Another example is creating a public, digital instructions of use (e-IFU) for medical devices so users and health professionals can easily consult instructions for safe reprocessing.*

Self-Regulation: This occurs when an organized group or industry regulates the behavior of its own members. It is highly recommended when there are no severe risks to public health and safety.

> ***Practical Example:*** *To prevent unethical interactions between medical device manufacturers and prescribing physicians, the authority might rely on a sector-wide "Code of Ethics" developed and monitored by the national association of medical device importers and distributors. The industry monitors itself, avoiding the need for the state to spend resources on continuous oversight.*

Co-Regulation: Also known as shared regulation, this occurs when the government establishes the broader safety or performance parameters but gives the regulated industry the flexibility to develop and administer the specific technical standards to achieve them.

> ***Practical Example:*** *When regulating Software as a Medical Device (SaMD), the authority required manufacturers to prove their software is safe and cyber-secure. However, instead of dictating the exact software architecture or coding language (which would quickly become obsolete), the regulator allowed companies to demonstrate compliance through recognized international standards (like ISO 14971 for risk management or IEC 62304 for software lifecycle) or through certifications issued by accredited third-party bodies.*

Economic Incentives: This involves altering the behavior of agents by changing relative costs, using taxes, subsidies, or tradable permits.

3. Normative Alternatives (Traditional Regulation): If non-normative avenues are insufficient to protect patient safety or mitigate severe risks, the authority must explore normative alternatives. Even here, you should map different degrees of stringency**.**

> ***Practical Example:*** *If hospitals are unsafely reusing single-use medical devices, a highly rigid normative option would be to completely ban the practice under penalty of fines. A more proportional normative option would be to update the Good Manufacturing Practices (GMP) and labeling rules, requiring manufacturers to provide clear traceability and validated instructions for reprocessing, thereby controlling the risk without prohibiting a practice that hospitals rely on financially.*

STEP 4: MAPPING THE INTERNATIONAL EXPERIENCE

As regulatory authorities, one of the most effective ways to build a high-quality Regulatory Impact Assessment (RIA) is to look beyond your own borders. Mapping the international experience is a strongly recommended step that allows you to analyze how other regulatory agencies and international organizations have previously addressed the exact same problem. This benchmarking exercise helps you avoid duplicating efforts, brings new perspectives, provides valuable data, and anticipates unintended consequences or market reactions to regulatory alternatives that have already been tested elsewhere.

In the fast-paced medical technology sector, this international mapping is absolutely crucial to achieve regulatory convergence. By aligning your national rules with international references, you reduce bureaucracy, facilitate economic development, and ensure that your market remains attractive to global technological innovations, all without compromising patient safety.[xiii]

a) **Benchmarking - Researching how other regulators have handled the problem:** When facing a regulatory challenge, you should investigate if there are similar international experiences and whether the solutions implemented by other countries can be adapted to your national context. This involves consulting peer agencies—such as the FDA in the United States, Health Canada, or European authorities—and reviewing their guidelines, manuals, and

regulatory frameworks. You can execute this by researching international databases, reviewing foreign legislation, or even sending direct questionnaires to foreign authorities.

> ***Practical Example:*** *When the Brazilian health authority (ANVISA) evaluated the risks of hospitals reusing single-use medical devices, they conducted a targeted international benchmarking exercise. By consulting international authorities, they found a wide variety of approaches: the FDA (USA) and Health Canada required third-party reprocessors to meet the same strict pre-market requirements as original manufacturers, while the European Union was shifting towards prohibiting the practice unless specific stringent conditions were me. Mapping these different international avenues provided the regulator with a solid, evidence-based foundation to build and compare their own regulatory alternatives.*

b) **Regulatory Convergence - Prioritizing international technical standards:** Instead of creating unique, isolated national rules that can inadvertently become technical barriers to trade, good regulatory practices encourage authorities to maximize the use of internationally harmonized standards. Adopting widely recognized frameworks—such as those from the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC), or the International Medical Device Regulators Forum (IMDRF)—simplifies compliance for manufacturers, reduces economic inefficiencies, and allows patients faster access to safe, cutting-edge technologies.

> ***Practical Example:*** *If you are designing a regulation for Software as a Medical Device (SaMD), creating a unique set of local technical requirements would quickly isolate your country from global software updates and innovations. A converged approach would involve adopting the harmonized definitions, clinical evaluation guidelines, and risk categorization frameworks already developed by the IMDRF. Furthermore, instead of inventing new testing protocols, you can co-regulate by requiring manufacturers to demonstrate safety and efficacy through established international standards, such as ISO 13485 for quality management systems, ISO 14971 for risk management, and IEC 62304 for software lifecycle processes. This approach guarantees a high level of patient safety while seamlessly integrating your country into the global medical device market.*

c) **The Global Scope of Regulatory Impact Analysis (RIA):** As regulatory authorities, it is crucial to understand that regulators do not regulate in a vacuum. In a highly interconnected global economy, domestic rules inevitably generate international ripple effects. Therefore, evaluating how a new regulation affects other countries and international stakeholders is not just a secondary step; it is a fundamental pillar of Good Regulatory Practices (GRPs). Various guiding documents explicitly list the "impact on international trade or the level of market openness" as one of the most relevant economic impacts that must be measured in your assessment.[xiv] It is also reinforced that the regulator must evaluate specific impacts on international trade, actively seeking to design regulatory alternatives that harmonize unnecessary regulatory differences with the rest of the world.[xv] When evaluating economic aspects, it is recommended calculating both the short- and long-term costs and benefits that the regulatory alternative will bring to "Other countries and international relations".[xvi] This

obliges the regulator to evaluate, for example, whether the proposed rule creates diplomatic friction or if it requires the revision of international agreements already signed by the Brazilian State. Additionally, when measuring the impacts of an alternative, the regulator should investigate whether there are critical distributional issues—that is, whether the costs of the new rule will be unfairly or disproportionately borne by any specific group, expressly including foreign "commercial partners".[xvii]

Practical Example 1: *Imagine that your agency identifies a safety flaw in a certain class of medical equipment and decides to propose a rule that severely restricts the importation of replacement parts from certain continents. When performing the RIA, your focus cannot be limited exclusively to the national territory. You must measure the impact of this restriction on international stakeholders (foreign manufacturers and exporters who will lose the ability to sell to Brazil) and the overall impact on the international trade balance. More importantly, you will need to analyze whether this strict rule violates existing global agreements, such as the Agreement on Technical Barriers to Trade (TBT) and the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS). If you fail to assess this international impact, your country might face severe commercial retaliations, diplomatic friction, and lawsuits from international trade partners. (Source: World Bank and Anvisa AIR Guide)*

Practical Example 2: *Imagine your health agency decides to impose a unique, highly restrictive domestic technical standard for the software used in imported MRI machines. Before drafting the legal text, your RIA must evaluate the impact on international stakeholders—in this case, foreign developers and manufacturers. If your new standard is too costly or completely incompatible with global programming standards, these foreign companies might simply stop exporting to your country. The unintended consequence? A severe shortage of critical diagnostic machines in your national hospitals. By assessing this international impact early, you can choose a regulatory alternative that adopts international standards (regulatory convergence), protecting your patients while keeping your market open to technological innovation. (Source: US Chamber of Commerce)*

What the International and National Guidelines Say	
The World Bank	*Highlights that the spectrum of impacts covered by a RIA must explicitly include the "impact on international obligations or agreements" as well as the "impact on competitiveness and market openness".*
The OECD	*Instructs that an in-depth analysis must be conducted whenever a regulatory decision is likely to result in "significant economic impacts, including on trade and investment".*
The U.S. Chamber of Commerce	*Lists the "Assessment of International Impact" as a mandatory checklist item for implementing GRPs. The document warns that duplicative, opaque, or conflicting regulations act as non-tariff barriers, which can be equivalent to a 20% tariff, severely hindering global trade and investment.*
Brazilian Guidelines	*(Ministry of Economy): Nationally, the guidelines instruct the regulatory team to actively investigate the international scenario during the RIA by asking: "Are there risks or unexpected reactions from agents at the international level when attempting to solve the problem?"*

STEP 5: COMPARISON OF IMPACTS AND RISKS AND INDICATION OF THE BEST SOLUTION

To make a high-quality regulatory decision, it is not enough to just list possible solutions; you must rigorously compare them. In this step, you will evaluate the positive effects (benefits or advantages) and negative effects (costs or disadvantages) of each alternative mapped previously, always using the "No Action" (status quo) scenario as your baseline for comparison.[xviii]

a) **Use of Evidence and Sound Science:** High-quality regulatory decisions depend entirely on high-quality data, as bad inputs inevitably lead to bad outcomes. Your analysis must be anchored in verifiable scientific data and technical integrity, prioritizing robust empirical evidence over mere opinions or assumptions.

> ***Practical Example:*** *If you are evaluating a new technical requirement for the sterilization of surgical equipment, do not rely solely on the opinions of hospital administrators. Instead, base your impact analysis on randomized clinical trials, systematic reviews of hospital infection rates, and concrete financial data on sterilization equipment costs.*

b) **Impact on Innovation and Competition:** The medical device sector is highly dynamic, characterized by short product lifecycles and frequent incremental innovations. When evaluating the costs of each alternative, you must carefully analyze whether the new requirements will create unnecessary barriers to entry or harm market competitiveness. Rigid, prescriptive regulations can inadvertently lock out new technologies and restrict the supply chain.

> ***Practical Example:*** *Imposing a strict, unified price cap on advanced implantable devices might seem like an immediate benefit for healthcare budgets. However, analysis often shows that this can drastically reduce the incentive for manufacturers to bring newer, safer, and more innovative technologies to your country, ultimately creating a risk of supply shortages and harming patients in the long run.*

c) **Comparison Methodologies:** To determine which alternative offers the greatest net benefit, you must apply a structured comparison methodology and clearly justify why that specific method was chosen for your analysis. The choice depends on the availability of data and the nature of the impact. Here some methods (without excluding others):

- **Cost-Benefit Analysis (CBA):** This method quantifies and monetizes all costs and benefits to calculate the Net Present Value (NPV). It provides a clear financial picture but can be challenging in healthcare, where monetizing the value of a human life is controversial. It is the main method indicated by the OECD. Example: Comparing the financial cost of a new software compliance rule directly against the monetary savings from reduced administrative errors in hospitals.

- **Cost-Effectiveness Analysis (CEA):** This is ideal when your primary benefits are vital to public health but difficult to monetize. It measures the financial cost required to achieve a single, non-monetary outcome. Example: Comparing alternatives based on the "cost per

adverse event avoided" or "cost per life saved". Cost-Effectiveness Analysis is recommended for the comparison of alternatives whose primary benefits are in the same unit of measurement or that have different types of benefits that can be transformed into a single index. The main difference between ACE and Cost-Benefit Analysis is the unit of measurement of the result. Examples of units of measurement in ACE: lives saved and contamination avoided. In the ACE, examples of measures are: years of life, years of life adjusted by quality (QALY) and years of life adjusted by disability (DALY). ACE is an important alternative to ACB when monetization of the most important impact is not possible.

- **Multicriteria Analysis (MCA):** Use this hybrid method when you have multiple, conflicting objectives that cannot easily be reduced to a single monetary value. You assign weights to different criteria (economic, social, safety) and score each alternative. Example: Scoring different diagnostic equipment rules based on patient safety (weight 5), compliance cost for SMEs (weight 3), and speed of technological adoption (weight 2).

Additional best practices to consider include distinguishing between economic/opportunity costs versus accounting costs and distinguishing transfer payments from costs/benefits.

Selecting Appropriate Methods for Valuing Life in Regulatory Impact Analysis

Valuing human life is one of the most complex and sensitive challenges you will face as a regulatory authority when conducting a Regulatory Impact Analysis (RIA). In practice, attempting to assign a financial value to a life encounters immense methodological difficulties and deep ethical questions regarding the "immorality" of pricing human life or the environment.[xix] Therefore, choosing the appropriate analytical method is a strategic step to firmly ground your decision and protect your agency from controversies.

When your regulatory proposal is primarily focused on preserving life, health, or safety, good regulatory practices strongly recommend using Cost-Effectiveness Analysis (CEA) as an alternative to the traditional Cost-Benefit Analysis (CBA).[xx]

***The Problem with Direct Monetization (Cost-Benefit Analysis - CBA):** Cost-Benefit Analysis requires that both the costs of the intervention and its effects be quantified and valued in monetary units. However, forcing a price tag on factors such as the "value of life" or an individual's time is a highly polemic and controversial subject. This controversy can easily derail a regulatory debate. Due to this inherent difficulty, it is common in CBA that some vital costs or benefits cannot be reliably measured in financial terms.[xxi]*

***The Practical Solution: Cost-Effectiveness Analysis (CEA)** To overcome the ethical and methodological hurdle of monetization, CEA emerges as the ideal and less controversial tool for evaluating health and safety interventions. Instead of converting a saved life into "Dollars" or "Reais", CEA allows the regulator to measure the benefit in its natural clinical or epidemiological unit.[xxii]*

The goal of the method shifts to finding out which option achieves the best health or safety outcome at the lowest financial cost. To structure this analysis, you can use globally established units of measurement:

- *Lives saved or accidents/contaminations avoided;*
- *Life-years gained;*
- *QALY (Quality-Adjusted Life Years);*
- *DALY (Disability-Adjusted Life Years).*

***Practical Example:** Imagine that your agency is deciding between regulatory actions that impose costs on toll road operators in order to reduce the number of accidents in critical road sections. Or, similarly, a new mandatory protocol in hospitals to reduce infections.*

Instead of calculating "how much" the life of a driver or patient is worth, you use CEA to calculate the mathematical ratio of cost per unit of effectiveness (e.g., money spent per life saved). If Rule A requires an investment of $15 million to avoid 200 accidents ($75,000 per accident avoided) and Rule B requires $30 million to avoid 500 accidents ($60,000 per accident avoided), Rule B presents a better cost-effectiveness ratio and should be the chosen alternative.[xxiii]

d) **Risk Matrices:** Distinguishing the Types of Risk: When comparing alternatives, you will encounter two distinct categories of risk that must be mapped using Probability vs. Impact matrices. It is vital for regulators to distinguish between them:

- Risk Analysis of the Alternatives (Regulatory Risks): This evaluates the intrinsic risks to society if the regulatory alternative fails to solve the market problem, or if it creates a new hazard (Risk-Risk analysis). Example: ANVISA considered that the option of price regulation is, in general, considered disproportionate, especially for micro and small companies, is too costly for the Agency and other agencies involved and with significant interference in the market structure, and it generates a severe new risk of market shortages and critical device unavailability.

- Risks Intrinsic to Implementation (Institutional Risks): This evaluates the risks associated with the regulatory agency's actual ability to enforce the chosen rule. Example: You design a highly sophisticated pre-market approval process for medical software, but the agency lacks the IT infrastructure, budget, and specialized software engineers to process the applications. This creates an implementation risk of massive administrative backlogs.

e) **Indication of the Best Solution:** After transparently applying your chosen methodology and evaluating the risks, the RIA must conclude with a clear, objective recommendation. You must indicate the preferred alternative (or combination of alternatives) that maximizes the net benefit to society, effectively solves the root cause of the problem, and is fully feasible for the regulatory authority to implement and monitor. Whether impacts are quantified/monetized or not, the analyst should also acknowledge and try to account for any explicit or unknown uncertainty in their expected results. Transparently communicating uncertainty is critical for decision-makers and stakeholders to understand the impacts of the rule.

STEP 6: PUBLIC PARTICIPATION AND TRANSPARENCY

For a Regulatory Impact Assessment (RIA) to be truly effective, it cannot be done behind closed doors. Public participation is a core pillar of good regulatory policy and is strongly recommended across all phases of the RIA process. As regulators, it is vital to understand that transparency and stakeholder engagement are not mere bureaucratic formalities; they are essential tools for gathering real-world evidence, understanding practical challenges, building trust, and ensuring that our rules are legitimate and naturally easier to comply with.[xxiv] Stakeholder engagement is also necessary to ensure that the proposed regulatory measures are effective in the real world and to avoid that they need to be retracted due to a lack of practical structuring. Stakeholder engagement in RIAs is also a cornerstone of democratic societies, leading to higher quality regulation and to societal support for effective public policies in a manner that is not overly burdensome and that is supportive of economic development.

Engagement should occur early and continuously, not just after the decision has been made. A common mistake in regulatory agencies is to draft a complete, finalized normative text and only then open it to the public for consultation. By that time, the regulator's mindset is often already fixed on a single solution, and stakeholders will naturally focus only on criticizing the specific legal text rather than helping to solve the root problem. Good regulatory practice demands that dialogue begins as early as possible, acting as a continuous effort throughout the stages of defining the problem, comparing alternatives, and implementing the solution.[xxv]

> ***Practical Example:*** *Instead of waiting to publish a finalized draft rule on the reprocessing of single-use medical devices, you should first publish a "Preliminary RIA Report" or a "Collection of Inputs". This allows hospitals, device manufacturers, and patient advocacy groups to debate whether the problem was diagnosed correctly and if the proposed alternatives are actually feasible in a hospital setting, long before any legal text is written.*

Early Consultation: Involve specialists and the health sector still in the phase of identifying the problem and alternatives. When you are taking the initial steps to understand a problem or map out possible solutions, the regulatory authority often faces knowledge gaps and information asymmetry. Early engagement allows you to embrace "regulatory humility"—acknowledging that the government does not hold all the answers or data. By consulting stakeholders like medical societies, equipment manufacturers, academic researchers, and health professionals from the very beginning, you collect valuable data and avoid creating rules that look good on paper but are impossible to implement in practice. Early consultation can also provide a more detailed understanding of potential quantitative costs and benefits of the regulation.

> ***Practical Example:*** *When the Brazilian health authority (ANVISA) was taking its first steps to regulate Medical Software (Software as a Medical Device - SaMD), it did not start by writing a rule. ANVISA first held workshops and sent targeted electronic questionnaires to a specific group of external stakeholders: software developers, academic experts, and healthcare professionals. This early, targeted consultation was designed strictly to map the root causes of the problem (such as diagnostic errors) and to explore international alternatives, ensuring the RIA was built on solid, real-world technological foundations from day one.*

Responsiveness: Analyze the contributions received and present justifications for the acceptance or rejection of suggestions. Participation is only meaningful if it is a genuine two-way dialogue. If stakeholders take the time and resources to provide data and suggestions, the regulatory authority has a duty to process this information and provide clear feedback. Unfortunately, studies of regulatory practices show that regulators often fail to provide analyses and justifications for why they accepted or rejected society's contributions. To ensure transparency and prevent regulatory capture (by non-technical external or internal influences), you must publish a consolidated response document after the consultation period. This document must explicitly state how the policy was influenced by the input, or, if a suggestion was rejected, provide a clear, technical justification for why it was not adopted.

> ***Practical Example:*** *Suppose you hold a Public Consultation on new requirements for custom-made medical devices, and you receive 50 contributions from the industry requesting a longer transition period to adapt to the new manufacturing standards. Your agency must publish a formal response. If you accept the suggestion, you explain that the data provided by the industry proved that the original timeline would cause critical supply shortages in hospitals. If you reject it, you must clearly justify that extending the deadline poses an unacceptable, immediate risk to patient safety, referencing the clinical evidence gathered in your RIA. This shows the sector that they were heard, that their data was evaluated, and that the final decision was objective and evidence-based rather than arbitrary.*

STEP 7: IMPLEMENTATION AND MONITORING PLAN

As regulatory authorities, it is vital to understand that your work does not end when a new rule is published. In fact, that is exactly when the practical work begins. An excellent Regulatory Impact Assessment (RIA) must guide the entire regulatory cycle, planning in advance how the chosen alternative will be put into practice and how you will continuously track its success in the real world.

Enforcement Strategy: Putting the rule into practice. To ensure compliance, your RIA must outline a clear, realistic implementation and enforcement strategy. You cannot simply assume that the regulated sector will immediately, or easily, comply with a new standard. Instead, you need to ask practical questions: How will this alternative be inspected? Do the affected actors (such as hospitals or foreign manufacturers) need a transition period (vacatio legis) to adapt their processes to the new rules? If so, how long of a period is reasonable?

Enforcement strategies—such as physical inspections, technical analyses, and targeted audits—are critical tools to guarantee that medical products and services deliver the necessary safety to patients. Furthermore, you must look inward and assess your own agency's capacity: Do your sanitary inspectors need specific training to understand the new technology? Do they have sufficient bandwidth to enforce new regulatory measures? Are your internal IT systems ready to process new data or product registrations? Are the costs of this enforcement proportional to the objectives you want to achieve?[xxvi] In the United States, the RIA would estimate the costs of enforcement/implementation (and various alternatives if relevant). This can help a regulator assess trade-offs in potential strategies.

> ***Practical Example:*** *If your agency decides to implement a new standard for the safety of custom-made medical devices, your enforcement strategy should not rely solely on applying immediate fines. It should include an initial phase of publishing educational materials and Q&A guides for the industry, ensuring your own inspectors are technically trained on the new manufacturing standards, and providing a clear transition period so that the supply of these critical devices to hospitals is not interrupted.*

Performance Indicators: Measuring success and reducing risks. To objectively evaluate if your regulation is effective, you must build a monitoring plan based on performance indicators. These indicators must be directly linked to the specific objectives you established back in Step 2 of your RIA.

A good performance metric must follow a few simple rules: it must be easy to understand, measurable using data that is actually available to your agency, and strictly relevant to the core problem. Critically, before the new rule takes effect, you must establish a "baseline". The baseline is your starting point—it shows the current severity of the problem so that, months or years later, you can compare the new data against it to see if the regulation actually improved patient safety.

> ***Practical Example:*** *Suppose you are regulating Medical Software (Software as a Medical Device). A weak indicator would be simply counting the "quantity of software registered per year". This tells you nothing about patient safety. A clear, effective performance indicator would be tracking the "rate of severe adverse events, morbidity, or deaths associated with diagnostic software errors". By measuring the baseline of these adverse events today, you can monitor the data over time to see if your new cybersecurity and validation requirements are successfully driving those hospital error rates down. If the indicator does not improve, your agency has the evidence it needs to adjust or revise the regulation.*

STEP 8: STRATEGY FOR ARR (EX-POST EVALUATION) AND REGULATORY STOCK REVIEW

To ensure that our regulations remain effective and relevant over time, we must plan an Ex-Post Evaluation, widely known as the Evaluation of Regulatory Results (ARR). This step prevents rules from becoming obsolete bureaucratic burdens and ensures they truly protect patient safety.

a) The Ex-Post Evaluation (ARR). The ARR is a systematic assessment conducted after a rule has been implemented to verify its actual effects. While your initial RIA relies on estimates and projections, the ARR looks at reality: it compares the originally intended objectives with the actual outcomes observed in the healthcare market and society. It aims to answer crucial questions: Did the rule solve the problem? Were the costs proportional to the benefits? Did it generate any unintended negative impacts? The indicators collected in step 7 will be fundamental to perform a quality ex-post evaluation.

> ***Practical Example:*** *Imagine you implemented a strict new standard for the manufacturing of custom-made orthopedic implants. An ARR conducted a few years later might reveal that while patient safety improved (the intended benefit), the compliance costs were so high that many small local manufacturers went bankrupt, causing a shortage of specific implants in regional hospitals (an unintended negative impact). Identifying this reality allows the regulator to act and adjust the rule.*

b) Schedule for the Periodic Review of the Regulatory Stock. The medical technology sector evolves incredibly fast. A rule that is highly effective today may become completely obsolete or create barriers to innovation in just a few years. Therefore, managing the "regulatory stock"—the entire set of normative acts currently in force—is a fundamental good regulatory practice.[xxvii]

Updating the regulatory stock involves the periodic examination of existing rules to verify if they are still pertinent and if they should be maintained, altered, updated, or revoked. When you decide to issue a new normative act, your RIA must explicitly record a maximum timeframe or schedule for when this specific rule will be revisited and evaluated.

Based on the findings of the ARR and this periodic review, the regulatory authority can decide on several clear outcomes:[xxviii]

i. **Maintenance:** Keep the regulation exactly as is, if the objectives are being met efficiently.

ii. **Revision with adjustments:** Make small or significant changes to fix implementation flaws or adapt the text to absorb new medical technologies.

iii. **Deregulation/Revocation:** Completely eliminate the rule if the regulatory problem no longer exists, or if the rule became an unjustified burden that hinders healthcare access.

By embedding this strategy into your RIA, you guarantee that your agency maintains an efficient, modern regulatory framework that naturally adapts to health innovation while rigorously protecting the public.[xxix]

STEP 9: FINAL REPORT AND COMMUNICATION (PLAIN LANGUAGE AND ADVERTISING)

The Final Regulatory Impact Assessment (RIA) Report is the closing act of your analytical process, serving as the definitive document that consolidates all the elements that subsidized your choice of the most appropriate regulatory alternative. It is crucial to remember that this report is not an academic paper, but a practical working document designed to guide decision-makers and communicate your agency's actions to the outside world.[xxx]

To empower your agency and ensure your regulation is understood and respected, this final step must focus heavily on accessibility, plain language, and absolute transparency.

a) Consolidation into a technical and accessible document. Your final report must present a logical sequence, allowing the reader to easily follow the chain of facts, arguments, and conclusions. It should bring together all the steps you have worked on — the problem definition, objectives, mapped alternatives, stakeholder consultations, impact appraisals, and implementation plans. To keep the main text focused and readable, highly complex technical details, deep methodological formulas, or extensive data tables should be moved to the annexes.[xxxi]

a) Executive Summary: Plain language for non-specialists. The Executive Summary is arguably the most important section of your report. Good regulatory practices dictate that it must be objective, concise, and written in simple, plain language accessible to the general public.

A common mistake is using the summary merely as an introduction. Instead, it must be a complete synthesis that makes perfect sense even if the reader—such as a hospital manager, a patient, or a journalist—does not read the rest of the lengthy report. It must clearly summarize the regulatory problem, the desired objectives, the considered alternatives, the recommended solution, and its expected impacts (costs and benefits). Account for any explicit or unknown uncertainty in their expected results. Transparently communicate such uncertainty, if that it the case.

To achieve true plain language, avoid excessive technical jargon, acronyms, and foreign terms; if technical definitions are strictly necessary, explain them immediately to avoid ambiguity. Furthermore, to make the communication even more accessible, it is highly recommended to use visual formats, such as infographics, diagrams, scorecards, and tables, to break up the text and illustrate the impacts clearly.

- ***Practical Example:*** **Avoid (Bureaucratic/Jargon):** "The selected normative alternative mitigates the informational asymmetry regarding the reprocessing protocols of Class III medical devices, imposing new Good Manufacturing Practices (GMP) compliance requirements on stakeholders."
- **Prefer (Plain Language):** "We identified that hospitals lacked clear instructions on how to safely clean and reuse complex surgical equipment, putting patients at risk of infection. To solve this, the new rule requires manufacturers to provide validated, step-by-step cleaning manuals with every product. This ensures patient safety while keeping hospital costs reasonable."

b) Methodological Transparency: Assumptions, data sources, and limitations. Because RIA is an evidence-based tool, public trust in your regulation depends entirely on the reliability of your data. The

final report must be completely transparent regarding the methods, data, and sources of information used, with the sole exception of legally confidential or trade-secret information.

You must explicitly document the premises, parameters, and hypotheses that shaped your analysis. To build external legitimacy, your data and methods should be presented so clearly that qualified third parties could theoretically reproduce your analysis and arrive at the same conclusions.

Equally important is embracing "regulatory humility" by explicitly acknowledging the limitations of your analysis. No RIA is perfect. You must clearly state any data gaps, the uncertainties surrounding your estimates, and the limitations of the methodologies you chose.[xxxii] Acknowledging these limitations does not weaken your report; rather, it demonstrates rigorous, unbiased scientific integrity.

> ***Practical Example:*** *If your agency is estimating the financial costs of a new cybersecurity standard for connected medical devices (like pacemakers), you must cite exactly where you got your cost data (e.g., "Data provided by the National Association of Medical Device Importers during the public consultation"). If you assumed that updating software takes an average of 10 hours of a hospital IT technician's time, explicitly state this assumption. Finally, be transparent about limitations: "Because this is a rapidly evolving technology, we lack long-term data on cybersecurity breach frequencies in rural clinics; therefore, our cost-benefit estimates are primarily based on data from large urban hospital networks."*

4. GUIDELINES AND *THRESHOLDS* TO DEFINE THE LEVEL OF COMPLEXITY OF A REGULATORY IMPACT ASSESSMENT (RIA).

The Good Regulatory Practices guides, both national and international, are categorical in indicating that the choice of methodology should always be guided by the Principle of Proportionality.[xxxiii] This means that the analytical effort, resources, and time your team spends on Regulatory Impact Assessment (RIA) must be strictly proportional to the magnitude of the problem and the expected impacts on society.

Attending to the Principle of Proportionality.[xxxiv] The principle of proportionality is not related to the need to carry out the RIA in full or not. It is related to the detail or depth of the analysis and must be considered in each of the steps listed. Practice and experience will highlight cases that require further analysis throughout the preparation of the RIA. In the most complex cases, the simplest level of analysis will not be able to satisfactorily identify and investigate all the factors relevant to decision-making.[xxxv]

As a regulatory authority, you don't have unlimited time or resources. Therefore, the golden rule is: the analytical effort, resources and time spent on the RIA must be proportional to the relevance of the problem and the size of the impact that the State's intervention will cause in society. Making proportional use of RIA ensures that the benefits of analysis are realized without creating a crippling bureaucracy for your own agency.[xxxvi]

To decide in a structured way whether the RIA will be simple or complex, you can carry out an initial step called "Screening", applying quantitative thresholds and qualitative criteria.

Tips for rating and deciding how complex your analysis is:

1. Using Quantitative Thresholds (Financial Thresholds). Many countries and organizations, such as the OECD, advise the use of explicit financial limits to frame the analysis. The authority can stipulate ranges of financial impact values (direct costs to industry or Net Present Value of the intervention) and the volume of people affected to dictate complexity**:**

a) Simple RIA (Low Impact/De minimis): When regulatory intervention has little complexity, low implementation risk, and affects a small number of actors, it is not necessary — nor recommended — to employ exhaustive mathematical modeling.

Possible methodologies: Qualitative methods of comparison, Minimum Cost Analysis (which calculates only the cheapest option) or the filling of simple matrices.

> ***Practical Example:*** Imagine that your agency realized the need to unify two bureaucratic product registration forms that are currently sent separately. This is a purely administrative change, which reduces costs and does not affect health or safety. In this scenario, a simple qualitative analysis, based on readily available data and focused on describing that the measure simplifies the life of the regulated, is perfectly adequate. Spending time on economic formulas here would be a waste of public money.

b) Medium Impact RIA: When the problem involves a considerable number of companies or citizens, it presents multiple factors to be considered and requires the quantification of data to ensure that regulation will bring the expected result.

Possible methodologies: Cost-Effectiveness Analysis (ACE) and Multicriteria Analysis (MCA).

> ***Practical Example (ACE):*** *You need to intervene to reduce the rate of infections caused by scalpel sterilization failures. It is difficult, and ethically controversial, to put an exact "financial value" on a life saved or a disease averted. In these cases, the Cost-Effectiveness Analysis is the most appropriate, as it allows you to calculate which alternative reaches the goal for the lowest financial cost (e.g., "how many dollars does each infection avoided cost") without forcing the monetization of the benefit.*
>
> ***Practical Example (AMC):*** *If you have conflicting goals—such as balancing the rigor in the safety of new medical equipment with the financial impact for small local factories—Multicriteria Analysis is ideal. It allows you to create a system of weights and scores, evaluating the performance of each alternative on different qualitative and quantitative fronts*

c) Complex RIA (High Impact): For problems of very high complexity, technological novelty or regulations that cause a massive financial impact on the entire production chain, intuition and purely descriptive methods are insufficient and put the agency at risk.

Possible methodologies: Cost-Benefit Analysis (CBA), often combined with Sensitivity Analysis. CBA is the "gold standard" recommended by OECD countries for severe interventions. It requires the quantification and monetization of all the costs and all the expected benefits.

> ***Practical Example:*** *If your agency intends to institute the price fixing (maximum ceiling) for imported cardiac implants, the impact on the economy and the risk of companies leaving the country are high. Here, CBA is essential. Your team will need to calculate the Net Present Value (NPV) of the alternatives over a horizon of, for example, 10 years, crossing the industry's revenue losses with the savings generated for the public health system. As there are many uncertainties in the futures market, the literature recommends applying Sensitivity Analysis with the CBA, testing how economic variations (e.g., the soaring dollar) would affect the success of its rule.*

If you don't have the exact financial data right from the start, you can base your decision on deepening the analysis using the following criteria:

- **Magnitude, Duration and Distribution of Impacts:** Will the rule affect the market permanently or temporarily? Does it disproportionately harm micro and small companies in favor of large ones? Does it seriously interfere with the public budget?
- **Novelty and Technological Innovation:** Are you dealing with a problem in which the agency has little or no experience (such as software with Artificial Intelligence or gene editing)? Are the alternatives considered irreversible in the market? If it is highly innovative, the Complex RIA may be the most suitable.

- **Sensitivity, Risk and Uncertainty:** Does the issue generate a lot of opposition in society or in Congress? Can regulatory failure lead to fatal accidents, shortages of essential products, or irreversible damage to the environment? Is there a lack of solid data and is scientific uncertainty high? If so, we are facing a Complex RIA.

How it works in practice in each scenario:

To decide on the method, you must evaluate three pillars: the technical capacity of your team to run the methodology, the real availability of quality data in the market, and the proportionality of the impact generated by the problem. There is no single superior methodology; The best technique is the one that brings clarity to your decision-making in a viable, reliable and proportional way to the challenge faced.

5. APPLYING THE STEP-BY-STEP TOOL

To apply our practical roadmap and demonstrate how the Regulatory Impact Assessment (RIA) adapts to the regulator's needs, real cases were selected and comparative summaries were prepared.

COMPARISON #1

Simple Case: Proposal on Custom-Made Healthcare Materials	Complex Case: Economic Monitoring of Health Products (such as implants and prostheses)
Identifying the Problem and Affected Actors (Step 1)	
The problem was excessive bureaucracy. The general rule required that every medical product have a prior standard registration. Because tailor-made materials for a specific patient did not fit this pattern, hospitals relied on lengthy exceptional prior authorizations, which delayed surgeries and access to treatment. The focus was to solve a procedural bottleneck that affected hospitals and patients.	O The problem was a serious structural market failure: the "widespread market dysfunctionality due to information asymmetry." No one (hospitals, SUS, health plans) knew exactly what the fair price of orthoses and prostheses was, leading to corruption, judicialization and abusive prices. The problem affected the entire economic network: global providers, the Ministry of Health, health plan operators, and patients' finances.
Defining the Objectives (Step 2)	
Direct and operational. The objective was to establish clear requirements to enable the manufacture and import of these tailor-made materials, ensuring "faster access to the treatment/device for the specific case of a patient".	Strategic and economical. The objective was to provide transparency to prices, allow technical comparison between similar products and facilitate the creation of reference prices for public and private purchases in Brazil, reducing market failure.
Mapping Alternatives (Steps 3 and 4)	
The intervention was obvious and normative. The mapped solution was to create a direct norm (exempting prior authorization and creating simple notification rules) combined with information actions, without the need to design multiple drastic market options.	The authority had to test heavy models. The first alternative was to keep the old ineffective rule (Status Quo). The second was the Rigid Economic Regulation, that is, the authority defining and setting a "ceiling price" for prostheses, as is already done with medicines. The third alternative was Economic Monitoring (Flexible Regulation), requiring the industry to report prices and attributes, so that the agency could publish transparent comparison panels.
Impact and Risk Comparison Methodology (Step 5)	
The qualitative method REMAI (Impact Mapping Report) was used. The regulator applied "traffic light" panels. When assessing the impact on the Agency itself (ANVISA), the traffic lights turned green, attesting that the rule would not require new physical IT infrastructure or hiring new servers (Human Resources). For the citizens, the traffic light was also green, indicating that the routine to access medical devices would be more efficient. No financial formula needed to be run.	It required a scientific arsenal. The regulator conducted a Pilot Study focused on coronary stents to prove that it was feasible to group products by characteristics. It then performed a rigorous Cost-Minimization Analysis, measuring the direct administrative costs to government (such as building IT systems) and industry. The analysis concluded that the "Rigid Regulation" of prices would cause a high financial cost of inspection and the risk of companies leaving the market (shortage of innovations). The winning alternative was Flexible Monitoring, which proved to be cheaper, easier to implement and promote healthy competition.
Implementation and Monitoring Plan (Steps 7 and 8)	

Simple Case: Proposal on Custom-Made Healthcare Materials	Complex Case: Economic Monitoring of Health Products (such as implants and prostheses)
Implementation is immediate by eliminating the previous bureaucratic requirement. As the routine of prior authorization no longer exists, the bottleneck is reduced, achieving the benefit almost at the time of publication of the rule.	The agency has put together a vast execution plan. It designed the creation of interactive virtual dashboards to publish prices, planned instruction guides for the regulated sector and included in the agenda the future Regulatory Outcome Assessment (ARR), to specifically measure whether price dispersion effectively decreased with the measure and whether there will be a need for tougher interventions in the future.

Note that the RIA tool served the decision-maker in both scenarios proportionally. In the simple case, it prevented the agency from wasting months calculating figures in a scenario where it only wanted to remove a bureaucratic step to save surgical patients. In the complex case, the simulations and the pilot study protected the market against a state intervention of price freeze that could drive innovations in prostheses away from the country.

COMPARISON #2

Simple Case: Grouping of implantable materials in orthopedics	Complex Case: Regulation of Medical Software
Identification of the Problem and Affected Actors (Step 1)	
The central problem was procedural and focused on a market bottleneck. There was a lack of regulatory predictability that prevented companies from registering innovative products in new forms of commercial presentation (such as sets or families of implants). This rigidity blocked access to technologies that minimize risk and reduce the patient's surgical time.	The problem was systemic, global, and disruptive. The existing sanitary rules had been created for physical equipment (hardware) and were incompatible with software, which are intangible products, of global virtual distribution and that undergo constant updates (versions). This gap generated an unacceptable risk to public health due to cyber vulnerability (hacker attacks on hospitals), interoperability failures, and critical diagnostic errors.
Defining the Objectives (Step 2)	
Surgical objective. The agency focused on reviewing and disciplining the technical requirements so that manufacturers and importers could bundle orthopedic implants at the time of registration, absorbing commercial innovations and maintaining safety.	Strategic and cyber protection objective. The focus was to establish a robust regulatory framework harmonized with international best practices to require cybersecurity testing and ensure the clinical performance of medical applications and programs used in diagnoses and treatments.
Mapping Alternatives and International Experience (Steps 3 and 4)	
The options were straightforward. The regulator concluded that the best way out was to update the regulation itself (RDC) combined with the publication of a "Questions and Answers" document, discarding the need to build extensive bureaucratic Guides to solve a clustering problem.	The authority had to study in depth the international experience (such as the FDA's performance in the USA and the guidelines of the IMDRF global forum). Based on this, it compared four different paths of intervention: (1) Product Certification by third parties, (2) Creation of a new Regulation (RDC), (3) Exclusive issuance of Guides, or (4) Creation of a Market Ranking model 10. Formal regulation was chosen because it provides more consistent rules.
Impact and Risk Assessment Methodology (Step 5) — The Big Gap in Effort	

Simple Case: Grouping of implantable materials in orthopedics	Complex Case: Regulation of Medical Software
The Impact Mapping Report (REMAI) was used, a Level 1 qualitative tool anchored in the MACBETH method. Instead of exhaustive monetary calculations, the agency used visual panels with "traffic lights" to indicate impacts. The traffic light pointed to positive impacts (green light) in all spheres: for the regulated sector, the rule simplifies and reduces the sending of information; for the agency, it does not require new IT infrastructure; and for inspection, it reduces human effort, as it formalizes a commercial practice (sale of kits) that previously generated unnecessary fines.	Required a deep level of scientific data collection and modeling. The team applied a rigorous Multicriteria Analysis, comparing the alternatives against weights such as "Implementation Difficulty", "Regulated Effort", "International Consistency" and "Sector Resistance". To measure the risks, the agency sent electronic questionnaires aimed at software developers, health professionals, hospitals, and academics. The data were tabulated in complex graphs to cross-reference the frequency and severity of failures (such as screen crashes, incorrect dose calculations, and cyber intrusions), technically supporting the need to require strict validation tests.
Implementation and Monitoring Plan (Steps 7 and 8)	
Implementation is designed to be immediate. The measure did not even provide for an adaptation period (*vacatio legis*) for the sector, since the changes would already apply organically to the new registration process flows in the electronic system. Monitoring will be done in a simple way, by counting regulatory acts.	Generated a vast implementation plan focused on cultural change. As the regulated product (software) is virtual, the agency foresaw the use of educational webinars, the requirement of internal validation by companies and, critically, the technical training of its own sanitary inspectors — who have historically been used to inspecting physical machines and factories, but not computer codes. As a post-market monitoring, periodic surveys were planned to be carried out with hospitals and users to confirm whether the standard effectively reduced the occurrence of interoperability vulnerabilities and adverse events.

The RIA should work in favor of the agency, not delay it. To unlock the orthopedics records, the completion of qualitative matrices at traffic lights was sufficient and efficient. On the other hand, to protect hospitals from insecure software, the regulator needed to invest months in data collection with society and in global technical alignment.

6. BRAZIL: EXAMPLES OF SIMPLE AND COMPLEX RIA

In Brazil, the guidelines of the Federal Government (Chief of Staff) and regulatory agencies recommend that the analyses be separated into two large groups: RIA Level I (Simple) and RIA Level II (Complex).[xxxvii]

Simple RIA Scenario (Level I). If, after applying the criteria above, you conclude that the intervention has low risk, is not novelty, and the financial impact is negligible, the agency will perform a Simple RIA.

What to do: You must meet the basic requirements of the report: identify the problem, map the actors, present the legal basis, objectives, map the alternatives, impact and comparison of the alternatives.

The tool: Instead of mathematical modeling, you can use qualitative methods, operating with simple visual scales (such as "traffic lights" indicating whether the impact is negative, tolerable, positive, or no impact).

Complex RIA scenario (Level II). If the thresholds indicate a high impact on the economy, strong uncertainties or extreme novelty, you as a regulator are obliged to go a step further.

What to do: In addition to the basic steps, the authority must carry out a deep mapping of the international experience (benchmarking), carry out complete risk management approaches (Probability vs. Severity) and monetarily measure the impacts on society.

The tool: This is not just about qualitative visual "traffic lights". The agency must use rigorous quantitative methodologies to base the decision, such as Cost-Benefit Analysis (calculating the Net Present Value of impacts), Cost-Effectiveness Analysis or statistical simulations (such as Monte Carlo Simulation for sensitivity analysis).

Cases analyzed by ANVISA considered Simple RIA (Level I)	
Characteristics of these analyses: They do not intend to exhaustively evaluate or financially quantify all the direct and indirect impacts of the proposal. Instead of complex calculations, these RIAs use tools based on qualitative judgments (such as the Multicriteria Decision Support Method - MACBETH), building scales and adopting simple visual panels — similar to traffic lights (with green, yellow, and red colors) — to indicate whether the impacts on the regulated sector, the agency, and the citizen are positive, tolerable, or negative.	
Custom-made Health Care Materials: Directly evaluates the exemption from extra allocation of human resources or infrastructure.	BRASIL. Agência Nacional de Vigilância Sanitária (ANVISA). Relatório de Mapeamento de Impacto – REMAI: Materiais de Uso em Saúde fabricados sob medida. Brasília: ANVISA.
Revision of RDC 55/2015 (laboratory tests on donors): This is a one-off update to fill a small bureaucratic gap on laboratory screening, evaluated qualitatively.	BRASIL. Agência Nacional de Vigilância Sanitária (ANVISA). Relatório de Mapeamento de Impactos – REMAI: Revisão RDC 55/2015 testes laboratoriais doadores. Brasília: ANVISA, 2019.
Use of Foreign Regulatory Authority analysis: Focuses on efficiency gains when accepting evaluations from other countries, using the qualitative matrix of REMAI.	BRASIL. Agência Nacional de Vigilância Sanitária (ANVISA). Relatório de Mapeamento de Impactos – REMAI: Critérios gerais para o aproveitamento de análise realizada por Autoridade Reguladora Estrangeira Equivalente. Brasília: ANVISA, 2021
Grouping of implantable materials in orthopedics: Aimed at adapting existing forms of registration, simplifying processes.	BRASIL. Agência Nacional de Vigilância Sanitária (ANVISA). Relatório de Mapeamento de Impactos – REMAI: Agrupamento de materiais implantáveis em ortopedia. Brasília: ANVISA, 2021.
Classification of medical devices in Mercosur: Direct effort to harmonize the rules internationally, without drastic market change.	BRASIL. Agência Nacional de Vigilância Sanitária (ANVISA). Relatório de Mapeamento de Impactos – REMAI: Revisão da RDC 36/2015 classificação de dispositivos médicos no Mercosul. Brasília: ANVISA, 2019.

Cases analyzed by ANVISA considered Simple RIA (Level I)	
Good Practices for Surplus Blood Plasma: Alignment of standards with the Mercosur region using objective impact questionnaires.	BRASIL. Agência Nacional de Vigilância Sanitária (ANVISA). Relatório de Mapeamento de Impactos – REMAI: Boas Práticas de obtenção, processamento, distribuição e uso de Plasma Sanguíneo Excedente. Brasília: ANVISA, 2018.

On the other hand, when the regulatory body plans to intervene directly in market prices, change the structure of monopolies, or approve measures that will cost millions to the private sector, the decision-making process requires scientific robustness and in-depth mathematical modeling. In these cases, qualitative judgments give way to empirical evidence and complex simulations.

Cases Considered Complex RIA	
Economic Monitoring of Health Products in Brazil (ANVISA): This is a typically complex RIA. The agency was faced with the dilemma of implementing heavy regulation (ceiling price control) versus flexible regulation (economic monitoring). To justify its technical choice, the authority did not limit itself to public consultations; it had to perform a rigorous Cost-Minimization Analysis projecting costs over a 10-year horizon. In addition, the team ran a "Pilot Study" in a real-world environment to validate the feasibility of the idea and conducted a sophisticated Cost-Benefit Analysis in partnership with a university, using "Monte Carlo Simulation" to calculate the Net Present Value (NPV) and be able to measure the uncertainties and risks of price variation in the market.	BRASIL. Agência Nacional de Vigilância Sanitária (ANVISA). Relatório de AIR sobre Monitoramento Econômico de Produtos para Saúde no Brasil. Brasília: ANVISA, 2020.
Interoperability of receivables registration systems (Central Bank of Brazil): This is an RIA aimed at tough economic regulation, involving competition and correction of market failures (such as information asymmetry and local monopolies). The authority used advanced economic methodologies to define price caps linked to inflation (IPCA) and to the measurement of efficiency (X Factor) of the financial entities involved. To arrive at the best regulatory alternative, the agency modeled demand elasticity, estimated marginal and equity costs and also built comparative models testing three different scenarios — the probable, the optimistic and the pessimistic (if companies left the market due to costs). They completed the process by validating the scenarios in a multicriteria matrix with mathematically weighted numerical weights.	BRASIL. Banco Central do Brasil (BCB). Relatório de AIR - Interoperabilidade dos sistemas de registro de recebíveis. Brasília: BCB, 2024.

As regulators, when you start a Regulatory Impact Assessment, the first strategic step is not to collect data unrestrainedly, but to assess the "size" of the intervention. Punctual reforms require simplified tools such as Level 1, while interventions in the economic core of the health chain require in-depth analyses, such as scenario simulations and quantitative cost-benefit.

7. REGULATORY IMPACT ASSESSMENT SELF-ASSESSMENT CHECKLIST

To ensure that your work generates maximum value for society and avoids unnecessary bureaucracy, below it is presented a Regulatory Impact Assessment (RIA) Self-Assessment Checklist. This roadmap is designed so that you, as a regulatory authority, can audit the quality and consistency of your own report before submitting it to the final decision.

The self-assessment is divided into 10 crucial dimensions, based on government and academic best practices of regulatory quality assessment.

1. Definition of the Regulatory Problem

An ill-defined problem will inevitably generate an ineffective norm. Your RIA must prove that the intervention is based on facts, not perceptions.

- Have you avoided defining the problem as the "lack of a regulation"? The problem must be a market failure, an unacceptable risk, or a real institutional bottleneck.
- Have the root causes and consequences been clearly mapped? Example: Instead of saying that the problem is "the absence of regulation for medical software", you have demonstrated that the root cause is "cyber vulnerability" and the consequence is the "risk of patient death or theft of hospital data".
- Have you described the expected evolution of the problem in the future (baseline scenario) if the agency does nothing?

2. Mapping of Affected Actors

Regulation affects different groups in different ways. The quality of your analysis depends on knowing exactly who wins and who loses from the intervention.

- Were all groups properly identified? Avoid generic terms like "society" or "the market." Example: Specify whether the impact will fall on public hospitals, multinational manufacturers, medical technology startups, or rare disease patients.
- Have you evaluated how the problem affects micro and small companies?
- Was it clear whether the affected actors themselves contribute to the worsening of the problem and whether they could adopt measures to minimize it?

3. Legal Basis

Your agency can only act where the law allows.

- Is there an explicit legal basis that gives your agency the power to act on this particular problem?
- Have you checked if there are other institutions (e.g., Ministries, other agencies) with competing or complementary competencies, avoiding shadowing of rules?
- Does the proposed rule comply with domestic legislation and international treaty obligations that your country has assumed constituting relevant international law?

4. Defining the Objectives

The objectives should guide the choice of the alternative and allow the measurement of the success of the standard in the future.

- Are the goals directly connected to the root causes of the problem?

- Are the objectives clear, unambiguous, and measurable?. Example: Instead of using a vague goal like "improve the regulatory environment," have you set a concrete goal like "reduce the wait time for release of custom-made orthopedic implants by 50%"?

5. Identification of Regulatory Alternatives

A good regulator does not only think about creating prohibitions or obligations; He seeks the most efficient solution.

- Did you necessarily include the alternative of "no action" (maintaining the status quo)?
- Have you explored non-normative alternatives (that don't involve creating a new hard rule)? Example: Did you consider education campaigns, industry self-regulation, or the use of economic incentives (such as creating a price monitoring dashboard to provide transparency to the market) before proposing price fixing?
- Were clearly unfeasible or disproportionate alternatives justifiably ruled out early on?

6. International Experience (Benchmarking)

International convergence reduces costs for industry and ensures faster access to healthcare innovations.

- Did you map out if a relevant international benchmark exists to deal with the same problem? Example: Have you checked if the IMDRF, ISO, IEC or other international bodies already have reference documents or standards for the regulation of medical software or tailor-made devices, to avoid the creation of a one-off country-unique regulation (legal unicorn)?
- Did you map out how other reference medical device regulatory authorities dealt with the same problem? Example: Have you checked if the FDA (USA), Australia (TGA), Health Canada, the European Union, Japan (PMDA), Singapore (HSA), et al already have guidelines and technical standards for the regulation of medical software or tailor-made devices, to avoid the creation of a one-off country-unique regulation (legal unicorn)?
- Was the measure notified to the World Trade Organization, and did the review of comments include those received from the WTO members as required under international law? The lack of such consultation can result in the measure constituting an unnecessary barrier to health and trade and being retracted.

7. Impact Assessment and Comparison of Alternatives

This is the essence of AIR: to demonstrate mathematically or logically which path generates the greatest net benefit to society.

- Have the impacts (costs and benefits, direct and indirect) of each alternative been surveyed for society, for the regulated sector and for the government?
- Have you assessed whether the alternative creates or expands barriers to entry, affects competition, or increases the regulatory burden (bureaucratic requirements)?
- Was a structured methodology used to compare the alternatives (e.g., Cost-Benefit Analysis, Multicriteria Analysis, Cost-Effectiveness)?
- Did you formally justify the choice of the comparison method? Example: If the benefits of regulating a medical device are difficult to price financially (such as "lives saved"), did you justify using Multicriteria Analysis (assigning mathematical weights to safety versus industry costs) instead of using monetary Cost-Benefit Analysis?
- Have you been fully transparent about uncertainty and did you attempt to address uncertainty in the analysis where possible?

8. Transparency and Public Participation

The regulation should not be done behind closed doors. Early engagement brings empirical data that the government does not have.

- Does your RIA Report have an Executive Summary written in simple, objective language free of excessive jargon, so that a citizen or lay hospital manager can easily understand the proposal?

Were the affected actors consulted during the preparation of the RIA (before the decision was taken and the standard written)? Example: Have you used Public Procurement Grants (TPS), industry dialogues, or electronic forms to collect cost data directly from factories and hospitals? Does the report provide reasoned responses to the contributions received, showing why they were accepted or rejected?

9. Risks and Unwanted Effects

Any state intervention carries the risk of worsening a situation or creating new secondary problems.

- Have you identified the intrinsic risks of failure in the implementation of the chosen alternative?
- Has a "Risk-Risk" analysis been performed to predict whether your standard will create a new accidental risk? Example: A very strict rule that requires millionaire adjustments in regional hospitals for the reprocessing of medical materials can generate the collateral risk of local shortages and cancellation of essential surgeries.

10. Implementation and Monitoring Strategy (Ex-Post)

The publication of the standard is not the end of the work, it is the beginning of its actual application.

- Have you clearly defined how the rule will be implemented and enforced?
- Is there a provision for a reasonable transition period or adaptation (vacatio legis) for the regulated sector?
- Have you defined exact monitoring indicators to measure the performance of the standard in the future? Example: The indicator should not be the "number of registered software" (which says nothing about effectiveness), but the "rate of reduction of serious adverse events caused by software" in the hospital network.
- An official deadline has been set for the Regulatory Outcome Assessment (ARR), where the agency will review whether the standard should be maintained, adjusted, or repealed?

By applying this checklist critically, you will ensure that your RIA Report fulfills its role as a technical shield for the agency, a transparency tool for society, and an engine for regulatory development and innovation.

8. REGULATORY IMPACT ASSESMENT FORM

Basic Identification:
1. **Theme/Project:**
2. **Responsible Area:**
3. **Elaboration Team:**
SECTION 1: Diagnosing the Problem
The starting point is not the norm you want to create, but the problem that needs to be solved.
1.1. What is the exact problem that is intended to be solved? (Do not define the problem as the "lack of a norm")
1.2. What are the root causes and consequences of this problem in society?
1.3. What is the expected evolution if the government does nothing (maintaining the status quo)?
Practical Example: Instead of "Lack of regulation for medical software", fill in "Failures in medical diagnostic software (cause) are generating incorrect reports and putting the lives of patients in hospitals at risk (consequence)".
SECTION 2: Affected Actors
Regulation affects the behavior of different groups. We need to map them.
2.1. Who are the economic agents, users and citizens directly affected by the problem?
2.2. How does the problem affect each of these actors and how do they contribute to its permanence?
Practical Example: "Patients (at risk of misdiagnosis); Software Developers (face legal uncertainty to invest); Sanitary Inspectors (do not have clear guidelines to inspect)".
SECTION 3: Legal Basis
The agency can only intervene where it has legal authorization.
3.1. Which law or decree assigns competence to our body to act on this problem?
3.2. Are there other institutions with competing competencies (e.g., Ministries, other Agencies) that require joint action?
Practical Example: "The Law creating the Agency, in its article X, determines the exclusive competence for the sanitary control of medical devices".
SECTION 4: Objectives of the Intervention
Where do we want to go with our work?
4.1. What is intended to be achieved? (Set goals that are clear, realistic, and attack root causes)
Practical Example: "Reduce the analysis time of imported materials by 30% in 12 months" or "Mitigate cyber vulnerabilities in 100% of high-risk medical software".
SECTION 5: Mapping Solution Alternatives
Strict regulation is not the only way out. What are our options?
5.1. Alternative 0: Maintenance of the Current Situation (Not Action).

Basic Identification:
5.2. Alternative 1 (Non-Normative): (e.g., education, economic incentives, self-regulation)
5.3. Alternative 2 (Normative): (Ex: Creation of a rigid regulation)
Practical Example: To solve failures in the reuse of hospital materials, the non-normative alternative might be "Develop an educational guide and a training campaign for hospitals", while the normative alternative would be "Totally prohibit reprocessing under penalty of a fine".
SECTION 6: International Experience
How did the best in the world solve this?
6.1. How have other international agencies (e.g., FDA, EMA) and multilateral organizations dealt with the same problem?
6.2. Is it possible to adopt regulatory convergence practices (global standards)?
SECTION 7: Impact Analysis and Comparison (The Heart of RIA)
Every choice has a price. Which path brings the highest net benefit?
7.1. What are the positive (benefits) and negative (costs) impacts of each alternative for companies, citizens and the Agency itself?
7.2. Which methodology was chosen to compare the options (e.g., Multicriteria Analysis, Cost-Benefit)? Justify.
7.3. What is the winning alternative (the most appropriate to solve the problem)?
SECTION 8: Public Participation
The regulation should not be done behind closed doors.
8.1. Which actors were consulted during the preparation of this RIA (e.g., meetings, forms, taking of subsidies)?
8.2. What were the main contributions received and how did they change (or not) our analysis?
SECTION 9: Implementation and Monitoring Strategy
The rule does not work alone. How will we make it work in real life?
9.1. How will the chosen alternative be implemented and inspected?
9.2. Is there a need for a period of transition (vacatio legis) or for the adaptation of our internal systems?
9.3. What indicators will be used to monitor whether the solution is working?
9.4. When will the standard or solution be reassessed (maximum period for Regulatory Result Assessment - ARR)?
Practical Example: The success indicator should not be "number of fines applied", but rather "rate of reduction in the number of hospital infections", to be reassessed in 3 years.

Usage Tip: You can parameterize this form in your agency's electronic process system. For low-financial impact or routine interventions, the team can fill in the fields in a qualitative and short textual form (Simple RIA). When faced with projects with high economic impact, the team uses the same form structure, but in Section 7 attaches the detailed cost-benefit calculations (AIR Complex).

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15 of June of 2026.

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[iii] A **market failure** occurs when the free market, operating on its own, fails to allocate resources efficiently, which prevents the achievement of maximum social welfare and justifies state intervention. (ANVISA Guide and Civil House Guide) For a regulatory authority, this concept is easily understood through practical examples, such as information asymmetry—where a medical device manufacturer holds significantly more technical knowledge about a product's risks than the patient—or when the high initial costs to enter a market create monopolies that make essential goods inaccessible. (ANTT Guide and Civil House Guide).

On the other hand, an **institutional failure** (which encompasses systemic issues) happens when public or private institutions function poorly or inefficiently, hindering the success of public policies. (ANTT Guide and Civil House Guide). In your daily practice, you will identify this when there is a lack of clarity or overlapping competencies between government agencies, when extremely rigid and outdated rules block technological innovation, or when a problem is so widespread—such as the lack of transparent pricing for medical implants across different states—that it affects the entire national health system and cannot be solved without coordinated federal regulation. (ANVISA Guide and Civil House Guide)

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